JUN 2 0 2000

K001559

510(k) Summary of Safety and Effectiveness for the Calcium Sulfate Pellets

Proprietary Name:	Calcium Sulfate Pellets
Common Name:	Calcium Sulfate
Classification Name and Reference	Unclassified
Device Product Code:	87 MQV, Calcium Sulfate, Preformed Pellet
For Information Contact:	Karen Ariemma Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677

The Calcium Sulfate Pellets are provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in approximately thirty to sixty days when used in accordance with the device labeling.

Calcium Sulfate Pellets are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Calcium Sulfate Pellets are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. Because the pellets are biodegradable and biocompatible, they may be used at an infected site.

Calcium Sulfate Pellets are fabricated from 98% (w/w) medical grade Calcium Sulfate Dihydrate ($CaSO_4 \cdot 2H_2O$) material mixed or added with 1% (w/w) polyvinyl pyrilodone (PVP), and 1% (w/w) stearic acid.

The substantial equivalence of the Calcium Sulfate Pellets is based on an equivalence in intended use, materials, design, and relative indications and contraindications to Osteoset® Pellets – Wright Medical Technology, Inc., Profusion™ Bone Void Filler – BioGeneration, Inc. and Stimulan™ Calcium Sulfate Bone Void Filler – Encore Orthopedics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

Ms. Karen Ariemma
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401

Re: K001559
Trade Name: Calcium Sulfate Pellets
Regulatory Class: II
Product Code: MQV
Dated: May 18, 2000
Received: May 19, 2000

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Donna R. Lochner -

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001559

Device Name: Calcium Sulfate Pellets

Indications For Use:

Calcium Sulfate Pellets are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Calcium Sulfate Pellets are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. Because the pellets are biodegradeable and biocompatible, they may be used at an infected site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Donna R. Vachuska

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001559